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5 MAY -6 P1:59

David P. Blanke
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dblank@vclaw.com

FACSIMILE TRANSMITTAL PAGE

DATE: May 6, 2003

Glenn A. Ballard, Jr.
Bracewell & Patterson

FAX: 713.221.1212

PHONE: 713.223.2900

TO: Marc Labgold
Kevin M. Bell
Patton Boggs (VA)

FAX: 703.744.8001

PHONE: 703.744.8000

TO: Richard J. Oparil
Patton Boggs (DC)

FAX: 202.457.6315

PHONE: 202.457.6000

PAGES: 14 (including this transmittal page)

CLIENT/MATTER: INV850/13000

FROM: David P. Blanke

MESSAGE: David Blanke's 05/06/03 letter further responding to 04/14/03 Oparil letter.

Hard Copy Follows ☐ Yes ☒ No

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May 6, 2003

By Fax

Mr. Richard J. Oparil
Patton Boggs L.L.P.
2550 M Street NW
Washington, DC 20037

Re: *Baylor College of Medicine, et al. v. Clontech Laboratories, Inc.;*
Cause No. 2001-61352

Dear Richard:

I am further responding to your April 14 letter. Earlier I wrote regarding the Ruobo Zhang exhibits. As to the '808 continuations, we will be producing the non-privileged documents on this issue. In the meantime, I am providing the accompanying preliminary amendment and notice of allowance from the PTO.

Very truly yours,

David P. Blanke

attachments

- c: Glenn A. Ballard, Jr. (*by fax; w/att.*)
- Kevin Bell (*by fax; w/att.*)
- Tracey B. Davies (*Firm; w/o att.*)
- M. Michelle Muller (*Firm; w/o att.*)
- Jason M. Powers (*Firm; w/o att.*)

MAY 06 2003 12:50 PM FR

SON & ELKINS 512 542 8612

#95382#91202457 P.03/14



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

APPLICATION NO/ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR/ PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
--------------------------------	-------------	--	---------------------

EXAMINER

ART UNIT	PAPER
----------	-------

47

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

--See attached--

Notice of Allowability

Application No.

09/122,384

Examiner

James S. Ketter

Applicant(s)

ELLEDEGE ET AL.

Art Unit

1636

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included
herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS
NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative
of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment of 10/3/02 and the IDS of 3/4/03.
2. ☒ The allowed claim(s) is/are 43-68.
3. ☒ The drawings filed on 20 March 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 3. ☐ CORRECTED DRAWINGS must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. <u>70-12</u> & <u>71</u> . | <input type="checkbox"/> Examiner's Amendment/Comment |
| <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | <input type="checkbox"/> Other |

JAMES KETTER
PRIMARY EXAMINER



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Washington, D.C. 20590

NOTICE OF ALLOWANCE AND FEE(S) DUE

21546 7190 04/22/2003
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HOUSTON, TX 77002-6760

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EXAMINER

KETTER, JAMES S

ART UNIT

CLASS-SUBCLASS

1636

415-004000

DATE MAILED: 04/22/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1998	STEPHEN J. ELLEDGE	RAY1364-010CIP	4340

TITLE OF INVENTION: RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION

APPL. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
unprovisional	NO	\$1300	\$0	\$1300	07/22/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1306.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☒ Applicant claims SMALL ENTITY status.
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail Box ISSUE FEE**
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EAS (703)746-4000

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 31586 7590 04/22/2003

VINSON & ELKINS, L.L.P.
1001 FANNIN STREET
2300 FIRST CITY TOWER
HOUSTON, TX 77002-6760

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 I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Applicant's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/12/1984	07/24/1998	STEPHEN J. ELLEDGE	BAY1364-010CIP	4340

TITLE OF INVENTION: RAPID SUBCLONING USING SITE-SPECIFIC RECOMBINATION

APPL. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1300	\$0	\$1300	07/22/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
KITTER, JAMES S	1636	435-000000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.303).

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- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/5B/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1	_____
2	_____
3	_____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY AND STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent)

☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

- ☐ Issue Fee
- ☐ Publication Fee
- ☐ Advance Order - # of Copies _____

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☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner is hereby authorized by check the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid fees due to the application identified above.

(Authorized Signature)

(Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant, a registered attorney or agent, or the assignee or other party in interest as shown by the record of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or renew a patent by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 15 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. There will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/122,384	07/24/1996	STEPHEN J. ELLEDGE	BAY1364-010CIP	4340
21386	7380	04/22/2003	EXAMINER	
KETTER, JAMES S				
ART UNIT			PAGE NUMBER	
1636				

VINSON & ELKINS, L.L.P.
1001 FANNIN STREET
2300 FIRST CITY TOWER
HOUSTON, TX 77002-6760

DATE MAILED: 04/22/2003

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
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Washington, D.C. 20531
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/12/34	07/24/1998	STEPHEN J. ELLEDGE	RAY1364-010CLP	4340
215M	7590	04/22/2003	EXAMINER	
VINSON & ELKINS, L.L.P. 1001 FANNIN STREET 2300 FIRST CITY TOWER HOUSTON, TX 77002-6760 UNITED STATES			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1836	

DATE MAILED: 04/22/2003

Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003: Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: <http://www.uspto.gov/main/howtofees.htm>.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

Vinson & Elkins
ATTORNEYS AT LAW

V&E

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Direct Fax 512-234-3377
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October 3, 2002

CERTIFICATE OF FACSIMILE

I certify that this correspondence is being transmitted on October 3, 2002, by facsimile to the Patent and Trademark Office in accordance with 37 C.F.R. §1.8.

October 3, 2002

Date

Timothy S. Corder

Assistant Commissioner for Patents
Washington, D.C. 20231

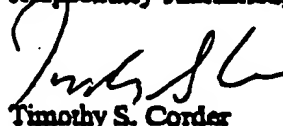
Re: U.S. Patent Application SN 09/122,384 "Rapid Subcloning Using Site-Specific Recombination," by Elledge et al.
Attorney Docket No.: BAY136/4-010CIP/36000; Client Ref.: OTA # 97-27
Confirmation No. 4340

Sir,

Enclosed for filing in the above-referenced patent application is a Preliminary Amendment for filing in the above-referenced patent application.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to appropriately deduct or credit the requisite amount from Vinson & Elkins L.L.P. deposit account No. 22-0365/BAY136/4-010CIP/36000.

Respectfully submitted,



Timothy S. Corder
Reg. No. 38,414

9282:5588

Enclosure

311728_1.DOC

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stephen J. Elledge et al.

Serial No.: 09/122,384

Filed: July 24, 1998

For: Rapid Subcloning Using Site-Specific
Recombination

Group Art Unit: 1636

Examiner: J. Ketter

Any. Dkt. No.: BAY136/4-10CIP/36000

Confirmation No. 4340

CERTIFICATE OF FACSIMILE

I certify that this correspondence is being transmitted on
October 3, 2002, by facsimile to the Patent and Trademark
Office in accordance with 37 C.F.R. §1.8.

October 3, 2002

Timothy S. Corder
Timothy S. Corder

PRELIMINARY AMENDMENT

VIA FACSIMILE NO. 703-746-5155

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In advance of prosecution, the Examiner is requested to please amend the above-captioned application as follows:

AMENDMENT

A. In the Claims:

Please cancel all pending claims, i.e. claims 1-20, 26, 30-35, and 37-42, and enter the following new claims:

43. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide.

44. The composition of claim 43, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
45. The composition of claim 43, wherein the composition comprises an enzyme activity with a Cre recombinase efficiency of about 16.8% per microgram of protein.
46. An isolated nucleic acid molecule comprising a coding region wherein the coding region encodes a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
47. The nucleic acid molecule of claim 46, wherein the coding region comprises the nucleic acid sequence of SEQ ID NO:10.
48. The nucleic acid molecule of claim 46, wherein the isolated nucleic acid molecule is an expression vector.
49. The nucleic acid molecule of claim 46, wherein the coding region is operatively linked to a promoter effective to direct expression of a glutathione-S-transferase-Cre recombinase fusion polypeptide.
50. The nucleic acid molecule of claim 49, wherein the promoter is an inducible promoter.
51. The nucleic acid of claim 50, wherein the promoter is the *tac* promoter.
52. A host cell comprising the nucleic acid molecule of claim 46.
53. A host cell comprising the nucleic acid molecule of claim 49.
54. The host cell of claim 53, wherein the host cell expresses a Cre recombinase activity.

55. The host cell of claim 53, further defined as an E. coli cell.
56. A bacterial cell engineered to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
57. The bacterial cell of claim 56, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.
58. A method of producing a glutathione-S-transferase-Cre-recombinase fusion polypeptide comprising:
obtaining an expression vector comprising a coding region encoding a glutathione-S-transferase-Cre-recombinase fusion polypeptide operatively linked to a promoter;
transforming or transfecting the vector into a cell; and
growing the cell under conditions effective to express a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
59. The method of claim 58, further comprising isolating the glutathione-S-transferase-Cre-recombinase fusion polypeptide.
60. The method of claim 59, wherein isolating the polypeptide comprises glutathione affinity chromatography.
61. A method of recombining nucleic acid segments, wherein each segment comprises a *lox* site specific recombinase site, the method comprising contacting the nucleic acid segments with a glutathione-S-transferase-Cre-recombinase fusion polypeptide.
62. The method of claim 61, wherein the polypeptide has an amino acid sequence according to SEQ ID NO:11.

63. A composition comprising a glutathione-S-transferase-Cre-recombinase fusion polypeptide and one or more nucleic acid molecules, wherein the nucleic acids comprise a site specific recombinase site.
64. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a lox recombination site upstream in a 5' to 3' orientation from an amino acid encoding region.
65. The composition of claim 63, wherein at least one of said nucleic acid molecules comprises a transcription regulatory element upstream in a 5' to 3' orientation of a lox recombinase site.
66. The composition of claim 64 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
67. The composition of claim 65 wherein the lox recombinase site is a *loxP*, *loxP2*, *loxP3*, *loxP23*, *loxP511*, *loxB*, *loxC2*, *loxL*, *loxR*, *lox486*, *lox4117*, or *loxH* site.
68. The composition of claim 64, wherein the amino acid encoding region is a member of a nucleic acid library.

II. REMARKS

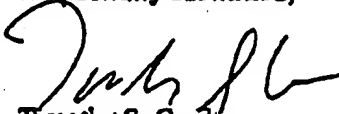
The claims in this preliminary amendment do not add new matter to the application and their entry is therefore respectfully requested. Support for the claims may be found throughout the Specification and at least in Example 3 found on page 47.

IV. CONCLUSION

Applicants respectfully submit that the present application and all claims are in condition for immediate allowance and early notice to such effect is earnestly solicited. If, in the opinion of the Examiner, a phone call may help expedite prosecution of this application, the Examiner is invited to contact the undersigned representative at (512) 542-8446.

It is believed that no fee is due; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Assistant Commissioner is authorized to deduct said fees from Vinson & Elkins L.L.P. Deposit Account No. 22-0365/BAY136/4-10CIP/36000.

Respectfully submitted,



Timothy S. Corder
Reg. No. 38,414
Agent for Applicant

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